Contemporary Clinical Trials Communications 12 (2018) 26–31

Contents lists available at ScienceDirect

Contemporary Clinical Trials Communications

journal homepage: www.elsevier.com/locate/conctc

Treatment of trauma related anger in operation enduring freedom, operation Iraqi freedom, and operation New Dawn veterans: Rationale and study protocol☆

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ARTICLE INFO

Keywords:
Veteran
Anger
Aggression
Trauma
Treatment

ABSTRACT

Background: Problems with anger and aggression are highly prevalent in Veterans of multiple war eras, including the most recent conflicts in Afghanistan (Operation Enduring Freedom; OEF) and Iraq (Operation Iraqi Freedom; OIF). The consequences of these problems, such as increased rates of divorce, domestic violence, occupational instability, arrests and incarceration, are often devastating. Despite the seriousness of these problems, relatively little is known about effective treatments for anger in Veterans.

Method and design: This paper describes the rationale and study protocol of a randomized controlled trial comparing an adapted cognitive behavioral intervention (CBI) with an active control condition (supportive intervention, SI) for the treatment of anger problems in OEF/OIF Veterans. The sample includes 92 OEF/OIF Veterans, randomized to CBI or SI. Both treatments include 12 weekly, 75-min individual sessions. Participants are assessed at baseline, after sessions 4 and 8, at post-treatment, and at 3 and 6 months post-treatment. Primary outcomes are reduction in anger and aggression; secondary outcomes are improved functioning and quality of life. We hypothesize that CBI will be associated with significantly more improvement than SI on primary and secondary measures.

Discussion: Findings from this study will help to address the gap in evidence for effective treatments for anger in Veterans. The use of an active control condition will provide a stringent test of the effects of CBI beyond that of common factors of psychotherapy such as therapeutic relationship, mobilization of hope, and support. Findings have the potential to improve treatment outcomes for Veterans struggling with post-deployment anger problems.

1. Introduction

Associations between combat and post-war problems with anger are well documented. Increased rates of anger have been shown among Veterans of multiple wars, including World War II [12,15], the Vietnam War [18,20], and more recently, the Afghanistan (Operation Enduring Freedom – OEF) and Iraq (Operation Iraqi Freedom – OIF) conflicts [13,14,29]. Reported rates of problematic anger or aggression in individuals having served in OEF/OIF have been as high as 57% in combat Veterans receiving VA medical care [29], and 67% in active duty soldiers 4 months after return from deployment [39]. The consequences of these problems can be devastating, including increased risk for divorce, domestic violence, job loss and instability, and other serious impairments in family, social, and occupational functioning [18].

Cognitive behavioral treatments for anger have been shown to be effective in civilian samples [2,7,8], but given the unique aspects of military training and combat that contribute to problematic anger, these findings cannot be assumed to generalize to Veterans. Military training involves responding to threat with aggression, aggression is powerfully re-enforced by survival, and repeated exposure to life threatening situations such as occurs in a warzone can result in a lower

☆ This research was supported by Grant Number 5I01RX001146, from the Department of Veterans Affairs, Rehabilitation Research and Development Program. The views expressed in this article are those of the authors and do not necessarily represent the views of the Department of Veterans Affairs.

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https://doi.org/10.1016/j.conctc.2018.08.011
Received 30 March 2018; Received in revised form 10 August 2018; Accepted 23 August 2018
Available online 24 August 2018

threshold for perception of threat and for anger reactions.

Despite the seriousness of anger problems among Veterans, little is known about effective treatments in this population. The few controlled studies to date have either had small sample sizes [3,32], or no control group [11,21,23]. We conducted a pilot study [32] of a cognitive behavioral treatment [24] that we adapted for OEF/OIF Veterans. This is the only study of anger treatment to our knowledge that has focused exclusively on OEF/OIF Veterans. Promising findings from this pilot led to the initiation of the current study.

The primary aims of this study (ClinicalTrials.gov ID: NCT02157779) are to test the efficacy of the adapted treatment, Cognitive Behavioral Intervention (CBI), on primary outcome measures of anger and aggression, and on secondary measures of functioning, quality of life, and PTSD symptoms at post-treatment and at 3 and 6 month post-treatment assessments. We hypothesize that CBI will be significantly superior to an active control condition on primary and secondary outcomes. Secondary aims are to examine mechanisms of action of CBI (hypothesizing that change in arousal, cognitive and behavioral domains of anger will mediate treatment outcome for CBI), and to explore the effects of CBI for those with and without PTSD. For the latter, we expect that the direction of effects will support superior outcome for CBI relative to SI for both those with and without PTSD. We also expect that participants with PTSD will show less improvement in both CBI and SI than participants without PTSD.

2. Methods

The study is a single blind randomized clinical trial (RCT) designed to test the efficacy of CBI compared to a supportive therapy comparison condition (Supportive Intervention – SI).

2.1. Participants

For study inclusion, participants were required to: (1) be current or former members of the military (active duty, National Guard, or Reserve), who served in OEF, OIF, or Operation New Dawn – OND); (2) endorse having experienced at least one DSM-5 Criterion A traumatic event while deployed; (3) report moderate or severe problems with anger and at least 2 additional symptoms from the PTSD hyperarousal symptom cluster as measured by the Clinician Administered PTSD Scale for DSM-5 (CAPS-5); (4) provide consent to be randomized and participate in the study; (5) agree to refrain from other active PTSD or CBT treatment, or any treatment focused on problems with anger during the intervention phase; and (6) if taking psychotropic medications, to have been on a stable dose for at least 4 weeks. Participants were excluded if they had any of the following: (1) DSM-5 substance or alcohol use disorder, severe (at least 6 criteria determined by the Structured Clinical Interview for DSM-5 Disorders (SCID-5); (2) psychotic symptoms, or mania or manic episode within the previous 3 months (determined by the SCID-5); (3) current suicidal or homicidal ideation requiring hospitalization (determined by follow-up clinical risk assessment by a licensed and credentialed provider upon positive responses to interview or self-report items regarding suicidal ideation); or severe cognitive impairment precluding the ability to comprehend interview questions (if suspected, to be confirmed by mental status exam).

2.2. Procedures

The study protocol was reviewed and approved by the Institutional Review Board of the local Veterans Affairs Medical Center. Participants were self-referred or referred by mental health clinicians throughout the mental health service of the VAMC. An initial screening procedure provided potential participants with information about the study, and asked questions regarding deployment (i.e., whether OEF, OIF, OND), and whether there had been any changes in psychotropic medications during the previous four weeks. Participants meeting initial screening were scheduled for an interview to further describe the study, obtain written informed consent for study participation, and to determine eligibility according to inclusion and exclusion criteria. Participants determined to be eligible then completed the rest of the baseline assessment, including additional interview and self-report measures. Participants were asked if they were willing to have a collateral reporter (significant other or other person with whom they had a minimum of 5 h of contact per week) to provide an additional perspective on change following treatment. Participants who agreed were asked to sign an additional consent to provide permission to contact the identified individual. Collaterals were fully informed of the study requirements and asked to sign informed consent.

Participants were randomly assigned to CBI or SI using urn randomization, a stratified randomization technique that systematically biases the randomization in favor of balance among the treatment condition on stratification variables [36,38]. Gender, PTSD diagnosis, and time since return from deployment (≤ 2 years vs. > 2 years) were used as balancing factors.

2.3. Outcome and mediator measures

Table 1 summarizes study measures and time of administration. Primary outcome measures for the study are the Anger Expression Index (AX-I) from the State-Trait Anger Inventory-2 (STAXI-2 [35]; and the Aggression Scale score from the Overt Aggression Scale-Modified (OAS-M; [4]. In addition to the baseline assessment, these measures are administered following the 4th and 8th treatment session, at the end of treatment, and at 3- and 6- month post-treatment follow-up assessments. Supplemental anger measures include the Anger Consequences

Table 1
Schedule of assessments.

Domain	Screening	Pre-Tx	Sessions 4 and 8	Post-Tx	Follow-up (3 and 6 months)
Inclusion/exclusion Criteria					
SCID	X				
CAPS	X			X	X
Sample Characterization					
SNAP-2		X			
CTQ		X			
Combat Exposure		X			
BSI		X	X	X	X
BAM (Use subscale)		X	X	X	X
Anger					
OAS-M[a]		X	X	X	X
STAXI-2[a]		X	X	X	X
ACQ[a]		X		X	X
DAR (weekly)					
Function/QOL					
LIFE psychosoc		X		X	X
OQ		X		X	X
WHOQOL-BREF		X		X	X
Mediators					
NAS arousal		X	X	X	
NAS cognitive		X	X	X	
NAS behavioral		X	X	X	
Other Measures					
Tx Satisfaction				X	
LIFE Tx section		X		X	X

Clinician administered interviews are in italics.
ACQ = Anger Consequences Scale; BAM = Brief Addiction Monitor; BSI = Brief Symptom Inventory; CTQ = Childhood Trauma Questionnaire; DAR = Dimensions of Anger Scale; *LIFE = Longitudinal Interval Follow-Up* Evaluation; NAS = Novaco Anger Scale; *OAS-M = Overt Aggression Scale Modified;* OQ = Outcomes Questionnaire; SNAP-2 = Schedule for Nonadaptive and Adaptive Personality-2nd Edition; STAXI-2 = State Trait Anger Inventory-2; WHOQOL-BREF = The World Health Organization Quality of Life.
[a] Collateral assessments are administered at pre- and post-treatment.

Questionnaire (ACQ [5,6]; and the Dimensions of Anger Scale (DAR; [10,26]), a brief 7-item self-report scale administered at each session. For collateral assessments, the STAXI-II, the ACQ, and the OAS-M interview were modified so that responses applied to the study participant. These measures were completed at pre and posttreatment.

Secondary outcome measures include global social and work functioning scales from the interview based Longitudinal Interval Follow-up Evaluation (LIFE; [17]), the total score from the self-report Outcomes Questionnaire (OQ; [19]), the WHO Quality of Life – BREF total score [33], and the CAPS-5 total score. These measures are administered at the end of treatment, and at 3- and 6-month follow-up assessments. Scales assessing arousal, cognitive, and behavioral domains of anger from the Novaco Anger Scale [25] are included to test mediator hypotheses.

2.4. Compensation

Participants were compensated for assessments as follows: $100 for the baseline assessment, $25 for each of the 4 and 8 - week assessments, and $60 for each of the end of treatment, 3 and 6 month follow-up assessments. Collaterals were compensated $25 each for the baseline and end of treatment assessments.

2.5. Treatment

Both treatments consisted of 12 weekly, 75-min sessions of individual therapy (allowing control for therapeutic contact). The term "Intervention" for each condition (rather than "therapy" or "treatment") was intended to aid recruitment and engagement in the study by reducing possible military-related stigma associated with receiving mental health treatment.

2.5.1. Cognitive behavioral intervention (CBI)

CBI was adapted from a cognitive behavioral treatment developed by Raymond Novaco [24], targeted at reducing anger frequency, intensity, and duration, and at moderating the expression of anger. Key elements include 1) psychoeducation (responses to trauma and to serving in a war-zone, trauma and war-zone related anger difficulties, stress, and aggression); 2) arousal reduction, including diaphragmatic breathing, and guided imagery training; 3) identification and cognitive restructuring of anger – related beliefs and interpretations; 4) behavioral coping strategies (training in communication, assertiveness, when and how to use "strategic withdrawal"); and 5) inoculation training (practicing the cognitive, arousal regulatory, and behavioral coping skills while visualizing progressively more intense anger-arousing scenes from personal hierarchies). Adaptations of the original [24] treatment for use with OEF/OIF veterans included addition of psychoeducation using "Battlemind", developed by researchers at Walter Reed [1]. Consistent with Battlemind principles, anger is conceptualized within the context of adaptive function in the warzone that becomes maladaptive at home. Additional emphasis on arousal reduction was added including breathing and guided imagery relaxation training administered in session and as homework. The manual was reorganized to facilitate therapist delivery including building in flexibility to allow the order of interventions to be adjusted if necessary. Finally, the option of a session involving a spouse or family member focused on psychoeducation was added.

2.5.2. Supportive intervention (SI)

SI was developed to provide an active control for non-specific treatment factors such as therapeutic relationship and support, enhancement of hope, and motivation to address problems. The SI manual used in this study was adapted from a present-centered supportive therapy manual developed by the first author for use as an active control condition for a multi-site study of prolonged exposure for the treatment of PTSD in female Veterans [31]. SI focuses on current life problems and is non-directive, with the content of sessions aside from the first two sessions determined by the patient. Interventions are supportive (e.g. active listening, reflection, validation) and problem-focused. Adaptations for the current study included revision of the framework of support and problem solving to fit the population of military personnel having served in Iraq or Afghanistan. The "Battlemind" psychoeducation component was also added. Cognitive behavioral interventions were proscribed.

2.6. Quality control

2.6.1. Therapist selection, training, and supervision

Therapists are Ph.D. level psychologists and a masters level clinical social worker with prior experience in cognitive behavioral therapy and in treating Veterans. Therapists deliver both treatment interventions. Initial training was didactic, including in person review of the manuals, as well as detailed review of required and proscribed interventions using examples and role-plays. All therapists completed one CBI training case, with supervision by the first author based on audio-recorded sessions. Since SI was restricted to supportive interventions, we did not require training cases. All therapy sessions in both conditions are audio-recorded. During early study cases, a random selection of 1–2 sessions of CBI and SI for each therapist was listened to and feedback provided as needed. Therapists initially met weekly as a group to discuss cases and receive supervision, transitioning to monthly meetings midway through the study. Treatment adherence is rated as described below.

2.6.2. Standardization of assessments

CAPs and SCID interviewers have masters or doctoral level training in psychology or social work and prior experience using structured interviews, with the exception of one BA level interviewer who had more than 15 years of experience conducting structured interviews in other studies, including in studies of OEF/OIF Veterans. A clinical psychologist (MKR) with previous formal training and experience with training others on CAPS administration provided CAPS training. The first author provided training on the OAS-M, using a detailed manual provided by the OAS-M developers [4]. Interviewers for the OAS-M also included two BA level research staff with prior experience conducting clinical interviews in Veteran samples. All interviewers conducted practice interviews and received feedback until judged to reach an acceptable standard of administration for both the CAPS and OAS-M.

Study interviewers are blind to participant treatment condition. All of the clinical interviews (CAPS, SCID, OAS-M, and LIFE) are recorded. Interviews were randomly selected on an ongoing basis to monitor the reliability of the interview process. Interviewers rated the audio-recorded interviews, and monthly meetings were held to discuss any discrepancies in ratings and to maintain reliability throughout the course of the study.

2.6.3. Treatment fidelity monitoring

Adherence scales were developed and applied during the pilot study and refined for the current study. The CBI adherence measure includes a checklist of designated interventions for each session, as well as a checklist to indicate possible use of CBI interventions from other sessions. The measure also includes global ratings of degree of adherence, ability to establish rapport, and overall therapist competence for the session. The SI adherence measure includes a checklist of required and allowable interventions for each session, a checklist of prohibited cognitive behavioral interventions, and similar global ratings for adherence, rapport, and competence. Two doctoral level psychologists with experience in treating Veterans and in cognitive behavioral therapy rate randomly sessions including a range of early, middle and late therapy sessions. To calibrate ratings, the first author and one or both of the raters completed ratings of the first 16 sessions selected for adherence ratings. Agreement was very good, with complete agreement

on required elements for 11 of the 16 sessions, and all but one of the global ratings across the 16 sessions agreeing either perfectly or within one point (poor, fair, good, excellent). Randomly selected sessions continue to be rated by both adherence raters for inter-rater reliability analyses.

2.7. Statistical analyses

2.7.1. Power analyses

Power for our repeated measures design was estimated using methods described by Faes et al. [40]. Our pilot study showed large between treatment group effect sizes [32], but given the small sample and the instability of effect sizes based on pilot studies [41], we based our power analysis for detection of medium effects. With a 2 sided alpha of .025 to account for multiple dependent variables, and an estimated 80% follow-up, our original power analyses indicated a sample size of 120 to reach 90% power for a medium effect size of 0.60. It became clear to us midway through the trial that a sample of 120 was not feasible within the recruitment time frame. We submitted a revised power analysis for review by the funding agency, which was approved. Our revised analysis indicated that a sample of 90 with 20% projected attrition would provide 83% power to detect a medium effect size of 0.60.

2.7.2. Data analysis plan

We will compare outcomes of the two interventions on an intent-to-treat basis, using all available data from the randomized study participants. We will also conduct supplementary analyses including only those cases completing at least 10 sessions.

For primary and secondary outcome measures, we will use hierarchical linear modeling (HLM) for repeated measures to test for differences due to treatment condition, covarying for the baseline score of the dependent variable [27]. The primary significance test will be the treatment group main effect over time, although there will also be a test for the time by treatment interaction. Significant time by treatment interactions will be followed up by post hoc tests at specific assessment points by calculating simple intercepts, simple slopes, and regions of significance. Relevant covariates will be included to adjust for any imbalances across treatment conditions. Hypothesis tests will be two-tailed with an alpha level of .025.

Despite consistent efforts to obtain post-treatment and 3 and 6-month follow-up assessments on participants who do not complete treatment, missing data is inevitable. HLM analyses can include cases with some time points missing. In the primary analysis, we will include all cases with at least 3 of the 5 outcome time points (4 and 8 weeks, posttreatment, and 3 and 6 months) non-missing. Then, we will conduct a sensitivity analysis including all randomized participants, in which missing outcome values will be filled in with last available outcome measure (including baseline scores for those with no assessments post-baseline). Consistency of results from the two approaches will bolster the credibility of the primary analysis. The alpha will be set at 0.025 to account for multiple dependent variables for primary and secondary outcome measure analyses.

Supplementary post-treatment outcome analyses will be conducted using collateral measures (STAXI-II, ACS and OAS-M). We will calculate Pearson correlations of participant and collateral scales as an indication of agreement. If correlations show low agreement, our plan is to conduct analyses using integrated collateral and participant scores, calculated by averaging participant and collateral responses to each item. As described below, our sample of collaterals is small. Nonetheless, if outcome analyses incorporating collateral measures are consistent with analyses of participant measures, this would bolster the validity of the participant outcome findings.

In order to examine the mediating role of arousal, cognition, and behavior, we will use NAS scales of arousal, cognition, and behavior at post-treatment as mediators of the effect of treatment in predicting later anger and functioning at months 3 and 6. Therefore, these mediation tests will be fully prospective, as recommended by Ref. [16]. These analyses will covary for the baseline scores of the mediators. Mediation of treatment effects through NAS scales will be tested using the Sobel test [22,34].

For our exploratory aim to examine the effectiveness of CBI for those with and without PTSD, we will test for an interaction between CBI vs. SI and PTSD status by calculating simple slopes. Since we will have limited power to test this interaction, we will calculate treatment effect sizes separately for the PTSD and the no-PTSD cases.

3. Current status

Recruitment for the study began in March 2015, and was completed in February 2018. Ninety-two participants were randomized, 47 to CBI and 45 to SI. Collateral participation was disappointingly low. Forty-seven participants identified a collateral and provided consent to contact; 27 collaterals completed the baseline assessment. Expected completion of the data collection for participants still active in the study is December of 2018.

4. Discussion

As with any clinical trial, certain design options required careful consideration. For studies of psychosocial treatments, choosing an appropriate control condition is one such consideration. Unlike medication trials, it is not possible to derive true “placebo” conditions that control for all aspects of the treatment delivery except the active ingredient (drug). A variety of control conditions have been used in behavioral treatment research, but there is no consensus regarding an optimal or standard control condition. There is increasing recognition that the design and selection of an optimal control condition depends upon the particular intervention being studied and the research question being addressed [30]. One important consideration is how much is known about the treatment being studied. Rounsaville et al. [28] outline a 3 stage framework including an initial stage (feasibility, pilot studies), RCTs/efficacy trials, and effectiveness studies. The current study would be considered a stage 2 efficacy trial according to this model; for such trials non-specific comparison designs have been recommended [30]. In addition to controlling for passage of time, testing, statistical regression towards the mean (all of which may be controlled for by a wait-list control), a non-specific comparison condition controls for the aspects of therapy that are common to most forms of therapy and are distinct from the hypothesized active mechanisms of the treatment being studied. This type of control allows for inferences about the benefits of the specific treatment interventions, beyond the benefits of for example, meeting with a therapist, receiving attention and support, and expectations of improvement. We adapted the manual for a non-specific comparison condition (Present Centered Therapy) developed for use in a large multi-site trial of treatment for PTSD in Veterans [31] for this purpose.

A second issue concerned the format of the treatment, i.e., delivered individually or in a group format. An advantage of a group format is the potential cost-effectiveness, and use of groups is common in VA mental health clinics. On the other hand, many patients are unwilling to participate in groups, and given the need to find a time that all potential group members can make, the logistics of group interventions can be challenging. This is particularly true for OEF/OIF/OND Veterans who often have time restrictions due to work and family. Logistics of RCTs of group treatments are also complex. The time required to recruit a sufficient number of participants to start groups means that participants have a longer wait time before starting treatment which can make retention difficult. Additionally, the inoculation training component of CBI, which involves using imagery of personalized anger inducing events and coping strategies, would be difficult to implement in a group format. It is also possible that individual delivery of anger treatment

may be more effective than group delivery given the greater amount of time and more intensive focus on an individual's anger themes, triggers, and cognitive distortions than is possible in individual treatment. Although to our knowledge there are no studies comparing individual vs. group treatment for anger problems in Veterans, it is of note that the new clinical practice guidelines recommend use of individual rather than group therapy for PTSD [37].

Another consideration was whether to restrict the sample to those with a PTSD diagnosis. Many studies report more severe anger problems in Veterans with PTSD than in those without, and it is possible that anger problems differ in other ways in those with and without PTSD. Further, two of the existing treatment studies of anger in Veterans required PTSD diagnoses [3,23]. On the other hand, significant anger problems associated with extensive social, occupational and legal impairment are also common in combat exposed Veterans without a PTSD diagnosis (e.g. Refs. [9,14]), and not requiring a PTSD diagnosis will make the findings relevant to a larger proportion of returning Veterans. We decided not to require a PTSD diagnosis for inclusion, but to require exposure to trauma during deployment, and the presence of at least three hyperarousal symptoms. This requirement is consistent with the conceptualization of anger as linked to hyperarousal in Veterans exposed to war-zone life threat. We included presence of a PTSD diagnosis as a balancing factor in urn randomization and will conduct exploratory analyses to examine whether treatment effects are the same for participants with and without a PTSD diagnosis.

A final consideration concerns the plan for collateral participation and assessments. Despite our best efforts, the participation rate was low. Many Veterans were unable or unwilling to identify potential collaterals, and only 57% of identified collaterals completed the baseline assessment. The low rate of participation may be due to characteristics of this sample, as anger problems are associated with a high degree of interpersonal conflict and isolation. Collaterals may be more likely to participate in studies that restrict inclusion to Veterans in an established relationship with a significant other.

5. Conclusions

Veterans who have served in war-zones are at high risk for problems with the experience and expression of anger that is often severe and disabling and results in serious impairment in functioning and quality of life. The costs of these problems are substantial not only to the Veterans themselves but also to their family members and society more generally. Although many VA clinics provide anger management groups, empirical evidence of efficacy of treatments for these Veterans is limited. This study was designed to address this gap using a randomized controlled trial design with an active control condition. Findings of the study may have important implications for treatment options for these Veterans.

Funding acknowledgement

This study is supported by a grant from the Department of Veterans Affairs Rehabilitation Research and Development Service (Award Number RX001146). The views expressed in this article are those of the authors and do not necessarily reflect the position or policy of the Department of Veterans Affairs or the United States Government.

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